



College of American Pathologists  
325 Waukegan Road, Northfield, Illinois 60093-2750  
800-323-4040 • <http://www.cap.org>

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Direct Response To:

DIVISION OF GOVERNMENT  
AND PROFESSIONAL AFFAIRS  
1350 I Street, NW, Suite 590  
Washington, DC 20005-3305  
202-354-7100 Fax: 202-354-7155  
800-392-9994 • <http://www.cap.org>

August 21, 2000

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD. 20850

RE: Request for Extension  
Docket No. OON-1394  
Medical Devices; CLIA Waiver Criteria

The College of American Pathologists is requesting an extension to submit written comments to the public docket on the FDA CLIA Waiver Criteria questions for public input as published in the Federal Register/Vol. 65, No. 141/Friday, July 21<sup>st</sup>, 2000. The request is to extend the time to submit written comments from September 14<sup>th</sup> to October 16<sup>th</sup>.

The reason for the extension is to provide adequate time for the College to perform a detailed review and analysis of the issues that need to be addressed. Thank you for your consideration.

Sincerely,

*David A. Mongillo*  
David A. Mongillo, Director  
Public Health and Scientific Affairs

*OON-1394*

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